

REMARKS

With the present supplemental response is submitted a Declaration under Rule 1.132 by Dr. Zenoviy Tkachuk, the named inventor in the present application.

This Declaration is being submitted to further support and illustrate that the nitrogen and/or phosphorus content of the yeast RNA product, as recited in present claims 20 and 55 (i.e., more than 14.5% by weight nitrogen and more than 8.5% by weight phosphorus), would not be obtained by a simple adjustment based on general knowledge of different purity levels for different purposes, as alleged in the Office Action.

Specifically, it was pointed out in the previously filed responses that the increase in nitrogen and/or phosphorus to contents as recited in the present claims results unexpectedly in a considerable increase in effectiveness of the anti-inflammatory action, as compared to a yeast RNA obtained by a conventional extraction process.

Thus, an increase in anti-inflammation activity of more than 50% is reported in the present specification using a conventional in vitro inflammation model, the thrombocyte aggregation model (see Example 2, Table 4 on page 31 of the present specification).

Further, it was shown that the cited prior art references do not provide any suggestion to increase nitrogen and/or phosphorus contents of a yeast RNA product, but rather, suggest that a conventional extraction process is adequate (see Kulkarni in particular, which is only concerned about the total nucleotide content, whether RNA or DNA). As a result, there would have been no motivation to further process an extracted yeast RNA to increase its nitrogen and/or phosphorus content.

The attached Declaration by Dr. Tkachuk reports on additional experimental results showing that a similar unexpected increase in anti-inflammation action is obtained using a conventional in vivo model.

Specifically, the in vivo local inflammation model in mice as described in Example 4.1 of the present specification was used. The results reproduced in Table 5-1 on page 2 of the Declaration show that the processing of the yeast RNA to nitrogen and/or phosphorus levels within the ranges recited in the present claims resulted in an unexpected increase by about 50% of the anti-inflammation effect (i.e., percentage of inhibition 53.5%) as compared to yeast RNA obtained by conventional extraction (i.e., percentage of inhibition 32.8%).

These results with the conventional in vivo inflammation model of Example 4.1 of the present specification are totally consistent with the results using a conventional in vitro model as reported in Example 2 of the present specification. These results further illustrate the unexpected improvement in anti-inflammation activity which is obtained by preparing a yeast RNA product containing more than 14.5% by weight nitrogen and more than 8.5% by weight phosphorus.

In summary, the nitrogen and/or phosphorus content of present claims 20 and 55 is neither taught nor suggested in any of the cited references, and provides unexpectedly improved anti-inflammation activity, as compared to conventionally extracted yeast RNA. Therefore, claims 20 and 55, and the claims dependent thereon, are not obvious over any combinations of the cited references.

In view of the above, it is submitted that the prior art rejections should be withdrawn.

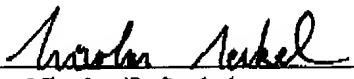
In conclusion, the invention as presently claimed is patentable. It is believed that the claims are in allowable condition and a notice to that effect is earnestly requested.

In the event there is, in the Examiner's opinion, any outstanding issue and such issue may be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of the response period. Please charge the fee for such extension and any other fees which may be required to our Deposit Account No. 01-2340.

Respectfully submitted,

ARMSTRONG, WESTERMAN & HATTORI, LLP

By: 
Nicolas E. Seckel
Attorney for Applicants
Reg. No. 44,373

Atty. Docket No. 000152

Suite 1000
1725 K Street, N.W.
Washington, D.C. 20006
Tel: (202) 659-2930
Fax: (202) 887-0357

NES:rep
Encl.: Declaration under Rule 1.132 by Dr. Zenoviy Tkachuk